



[BILLING CODE 4140-01-P]

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Proposed collection; 60-day comment request

National Institute of Neurological Disorders and Stroke FITBIR Data Access Request

AGENCY: National Institutes of Health, HHS

ACTION: Notice.

SUMMARY: In compliance with the requirement of the Paperwork Reduction Act of 1995, to provide opportunity for public comment on proposed data collection projects, the National Institute of Neurological Disorders and Stroke (NINDS), will publish periodic summaries of proposed projects to be submitted to the Office of Management and Budget (OMB) for review and approval.

DATE: Comments regarding this information collection are best assured of having their full effect if received within 60 days of the date of this publication.

FOR FURTHER INFORMATION CONTACT: To obtain a copy of the data collection plans and instruments, submit comments in writing, or request more information on the proposed project, contact: Dr. Sophia Jeon, Health Science Policy Analyst, Office of Science Policy and Planning, OSPP, NINDS, NIH, 31 Center Drive, Building 31, Room 8A03, Bethesda, MD 20892, or call non-toll-free number (301) 435-7571, or E-mail your request, including your address to: sophia.jeon@nih.gov Formal requests for additional plans and instruments must be requested in writing.

SUPPLEMENTARY INFORMATION: Section 3506(c)(2)(A) of the Paperwork

Reduction Act of 1995 requires: written comments and/or suggestions from the public and affected agencies are invited to address one or more of the following points: (1)

Whether the proposed collection of information is necessary for the proper performance of the function of the agency, including whether the information will have practical utility; (2) The accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) Ways to enhance the quality, utility, and clarity of the information to be collected; and (4) Ways to minimize the burden of the collection of information on those who are to respond, including the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology.

Proposed Collection Title: National Institute of Neurological Disorders and Stroke FITBIR Data Access Request, 0925-0677, REINSTATEMENT with change—, Expiration Date 12/31/2019 National Institute of Neurological Disorders and Stroke (NINDS), National Institutes of Health (NIH).

Need and Use of Information Collection: The FITBIR Informatics System Data Access Request form is necessary for Principal Investigators (PIs) and their organization or corporations with approved assurance from the DHHS Office of Human Research Protections to access data or images from the FITBIR Informatics System for research purposes. The primary use of this information is to document, track, monitor, and evaluate the use of the FITBIR datasets, as well as to notify interested recipients of updates, corrections or other changes to the database. For reinstatement of this collection, the agency proposes to add Data Submission Request to allow "Submitter" Principal Investigators (PIs) to request submission of their data to the FITBIR database for broad

data sharing and to document, monitor, and track the FITBIR data submissions. Types of respondents affected by this information collection are researchers, such as “Recipient” PIs who are interested in obtaining access to study data and images from the FITBIR Informatics System for research purposes, or “Submitter” PIs who are interested in submitting data to contribute to the FITBIR database for their data to be shared with the traumatic brain injury research community.

OMB approval reinstatement is requested for 3 years. There are no costs to respondents other than their time. The total estimated annualized burden hours are 96.

Estimated Annualized Burden Hours

| Form Name | Type of Respondents | Number of Respondents | Number of Responses per Respondent | Average Burden Per Response (in hours) | Total Annual Burden Hours |
|--------------------------------|---|-----------------------|------------------------------------|--|---------------------------|
| FITBIR Data Access Request | Individuals (“Recipient” Principal Investigators) | 85 | 1 | 60/60 | 85 |
| FITBIR Data Submission Request | Individuals (“Submitter” Principal Investigators) | 65 | 1 | 10/60 | 11 |
| Total | | | 150 | | 96 |

Dated: November 14, 2019

Paul Scott

Project Clearance Liaison

National Institute of Neurological Disorders and Stroke, NIH

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